IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SAGE CHEMICAL, INC., *et al.,*	)	
	)	
Plaintiffs,	)	
	)	C.A. No. 22-1302- CJB
v.	)	
	)	**JURY TRIAL DEMANDED**
SUPERNUS PHARMACEUTICALS, INC., *et al.*,	)	[redacted]
	)	PUBLIC VERSION FILED
Defendants.	)	NOVEMBER 16, 2023

DEFENDANTS' LETTER TO THE COURT REGARDING REQUEST FOR AN EXTENSION TO THE SUBSTANTIAL COMPLETION OF DOCUMENTS DEADLINE

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Counsel for Defendant Britannia Pharmaceuticals Ltd.

Dear Judge Burke,

Pursuant to the Court's November 6, 2023 Oral Order, D.I. 189, Defendants submit this letter in support of a requested amendment of the Scheduling Order, D.I. 98, and state as follows.

Defendants satisfy the "'good cause" standard under Fed. R. Civ. P. 16(b)(4), which requires both "an explanation of why more time is needed" and a showing of diligent efforts made at discovery. *Walker v. Centocor Ortho BioTech*, 558 F. App'x 216, 221–22 (3d Cir. 2014). As set forth below, the parties have worked diligently to complete discovery, but given the size and scope of the case, discovery is taking longer than anticipated.

As the Court has said from the beginning of this case, "this is a large and complex litigation with many parties and issues at play." D.I. 79. The extensive discovery that has taken place over the intervening months has proven this to be right. The parties have collectively served over 130 document requests and 32 third-party subpoenas, among other discovery, and have participated in more than 30 meet and confers. This has included time-consuming discussions over issues like the "technology assisted review" protocol and search terms, including initial proposals from Plaintiffs that were extraordinarily broad and required extensive discussions to work toward agreement. *See* Exs. 1 & 2. Document discovery has taken months, and there is still more work to be done by both sides.

Defendants are advancing document discovery in good faith, but the realities of the case have overtaken the parties' best expectations when proposing the Scheduling Order months ago. Furthermore, given the number of potential documents, parties, and issues, Defendants respectfully submit that the interests of judicial efficiency would be best served at this stage by obtaining the Court's guidance through rulings on the motions to dismiss, which may impact the pending claims and corresponding discovery. For these reasons, a modest 60-day extension of the deadline for substantial completion of document production from December 1, 2023 to February 1, 2024 is both necessary and appropriate, and will not unduly prejudice any of the parties. Below, Defendants provide a summary of their individual discovery efforts to date.

Supernus. Through the end of October, Supernus Defendants produced 1,656 documents across nine productions totaling 20,450 pages. They have offered 11 custodians, including two custodians who are offered both for Supernus and US WorldMeds (going back to 2015), for TAR. While Plaintiffs' initial search terms would have yielded over 500,000 direct hits from these custodians, Supernus engaged in good faith negotiations over several weeks that resulted in a set of 211,760 hits, or about 227,000 family documents for TAR review. Supernus began its TAR on September 19, 2023, and its reviewers have already laid eyes on over 110,000 documents. Supernus will make its first TAR production on November 10, 2023, and expects to make additional and larger productions at one or two week intervals, from this point forward until the TAR is concluded. Though there is quality control and cleanup to do, Plaintiffs will receive tens of thousands of documents from the Supernus Defendants in the coming weeks. But the Supernus Defendants need several additional weeks to responsibly accomplish substantial completion.

Britannia. Britannia has diligently participated in discovery, subject to and despite various burdensome rules that apply only to Britannia as a UK-based company. Britannia has:

(i) responded to 62 document requests; (ii) served 60 document requests; (iii) responded to two sets of interrogatories and amended its responses to the first set; (iv) served interrogatories; (v) collected and undertaken review of documents from custodians likely to have relevant information; and (vi) participated in dozens of meet and confers. As of this writing, Britannia has produced 227 documents. Britannia does not dispute that other parties have produced more documents to date. But that should come as no surprise to Plaintiffs, as Britannia has repeatedly advised Plaintiffs of the unique privacy challenges it faces. After weeks of working with separate UK privacy counsel, Britannia received clearance to make its first custodial production the week of October 30, just a few weeks after Plaintiffs made their own first significant production. And Britannia has over 30 contract attorneys reviewing thousands of documents in the UK in anticipation of making rolling productions. Britannia will continue to make such productions and, like the other parties in this case, is working diligently to comply with all Court deadlines.

USWM Defendants. The USWM Defendants—former corporate affiliates and employees of the entity operating the Apokyn business—believe they are not proper parties to this case, as explained in their motions to dismiss. *See* D.I. 48, 50, 54, 55. But they have nonetheless proceeded in good faith with discovery. Plaintiffs regrettably opted for an excessive broad approach to discovery of the USWM Defendants, with requests spanning almost a decade —including 2014, eight years before Plaintiffs even entered the market. After Plaintiffs served their main set of document requests in May 30, 2023, it predictably took many months for the parties to resolve or narrow their disputes over scope and to negotiate search terms. Notwithstanding these substantial differences of opinion between Plaintiffs and the USWM over scope, the USWM Defendants began reviewing documents before reaching final agreement with Plaintiffs on search terms or scope, and began producing substantial amounts of ESI on October 11, before Plaintiffs did so (even though Defendants served their primary document requests before Plaintiffs did). The USWM Defendants have produced over 500 documents (more than 6000 pages), and anticipate producing thousands more before December 1. However, the documents and issues in this case involve highly complex issues, including regulatory filings that involve potential privilege concerns. The USWM Defendants believe that, particularly given the pendency of their motions to dismiss, as long as significant progress is being made—which it absolutely is—and the parties have agreed to continue to produce documents in good faith, and on a rolling basis, it is both unnecessary and unwarranted to impose the significant and undue costs on the USWM Defendants that would be required to substantially comply by December 2023.

Third Party Discovery. Document requests to third parties have been substantial in this case, from both sides, with a total of 32 subpoenas served thus far. Third parties have been slow to respond to and comply with subpoenas and will be nowhere near complete with their productions in advance of December 1, 2023. Furthermore, Defendants continue to learn of additional key nonparties, undisclosed by Plaintiffs, who were heavily involved in roles such as finding Sage's marketing partner, matching Sage with potential manufacturers of an alternative apomorphine injector and/or serving as a manufacturer of such an injector, or partnering with Sage on development of its own generic injector/cartridge product.

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Exhibit 1

PUBLIC VERSION FILED
NOVEMBER 16, 2023

Buck, Tracy B.

From: Duxstad, Lauren <LDuxstad@winston.com>
Sent: Wednesday, May 31, 2023 6:04 PM
To: Shotlander, David S.; Silver, Daniel; Joyce, Alexandra; Moskow-Schnoll, Beth; Streifthau-Livizos, Michelle C.; Rosenfeld, Jordan D.; Burns, Tyler; Brockmeyer, Michael; Vakharia, Aakruti G.; Labaton, Ralph E.; Lipkin, Gary W.; Monk, II, Charles O.; Robbins, Jeffrey S.; Moore, Daniel M.; Danilewitz, Justin C.; Dobie, W. Gordon; Golden, Kaitlyn A.; Kattan, Ilana; Levin, Adam K.; Holt, Benjamin F.; Strauss, Nathan; Stock, Eric J.; Obear, Joshua; Steinhauer, Holden A.
Cc: Dobie, W. Gordon; Torpey, Susannah; Knoepfler, Aliana C.; Jennifer L. Cree; Rebecca Butcher; Dan Rath
Subject: Sage Chemical et al. v. Supernus et al. - TAR Protocol
Attachments: TruPharma - Draft Search Term and TAR Protocol.docx

This Message originated outside your organization.

Counsel,

Attached please find a draft search term and TAR protocol. Please let us know if you have any comments by next Wednesday, June 7.

Best,
Lauren

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Sage Chemical, Inc. and TruPharma, LLC, *Plaintiffs*, v. Supernus Pharmaceuticals, Inc., *et al.*, *Defendants*.	Civil Action No. 1:22-cv-01302-CJB

STIPULATED PROTOCOL AND [PROPOSED ORDER] RELATING TO THE USE OF SEARCH TERMS AND TECHNOLOGY-ASSISTED REVIEW TO REVIEW DOCUMENTS ("TAR PROTOCOL")

Sage Chemical, Inc., TruPharma, LLC, Supernus Pharmaceuticals, Inc., Britannia Pharmaceuticals Limited, US WorldMeds Partners, LLC, MDD US Enterprises, LLC (f/k/a USWM Enterprises, LLC), MDD US Operations, LLC (f/k/a US WorldMeds, LLC), USWM, LLC, Paul Breckinridge Jones, Herbert Lee Warren, Jr., Henry van den Berg, and Kristen L. Gullo (collectively, the "Parties"), by and through their respective counsel, hereby stipulate and agree to the terms of this Protocol to describe the process to be used for conducting a Technology-Assisted Review ("TAR") of certain electronically stored information ("ESI") in the above-captioned matter. The Court hereby adopts the Parties' TAR Protocol as follows.

1. Definitions

a. "Action" shall mean the case assigned Civil Action No. 1:22-cv-01302-CJB, "*Sage Chemical, Inc. et al. v. Supernus Pharmaceuticals, Inc. et al.*," filed in the United States District Court for the District of Delaware on October 3, 2022.

b. "Producing Party" shall mean the party delivering to another party, or making available for that party's review, documents and/or ESI.

c. "Receiving Party" shall mean the party receiving, or having another party make available for

its review, documents and/or ESI.

d. "Search Term" shall mean a word, phrase, or combination of a word or phrase using one central Boolean connector. For example, a term could be pizza, "pizza pie", or (pizza w/3 pie). In the following instance, there are six search terms: (pizza OR pie) AND (pepperoni OR cheese OR mushrooms).

2. Identification of Search Terms

a. The Parties will utilize agreed-upon search terms to narrow the set of all collected ESI, including any custodian data sources, for review prior to utilizing any TAR tool, as outlined by the process herein.

b. The Producing Party will provide the list of search terms that may be applied by the Producing Party against any set(s) of non-structured ESI that would be subject to further review ("ESI"). The search terms will be developed in good faith to reasonably identify potentially responsive documents and will not be designed to purposefully avoid known responsive documents.

c. The Producing Party will disclose the sources of non-structured ESI that it proposes to run the search terms on, including any custodian data sources.

d. As part of the meet and confer process, the Producing Party will run the proposed terms against the ESI of disclosed custodial sources, recognizing that additional sources of data may ultimately be subject to discovery. The Producing Party will provide a search term hit report to the Receiving Party. The report should include the total number of documents subject to search, the names of the custodians subjected to the search, the number of documents that hit on each term by custodian, the number of unique documents that hit on each term (documents that hit on a particular term and no other term on the list), and the total number of documents that would be returned by using the proposed search term list (including families).

e. Within seven (7) business days of the receipt of such search terms, or a date mutually agreed to by the Parties, the Receiving Party will specifically identify, in writing, any proposed

additions, changes, comments or questions regarding the proposed search terms. Because the Parties will be using TAR in addition to search terms, it is understood that the search terms may be broader and more numerous than would typically be used where search terms alone are being used to identify potentially relevant documents.

f. Within fourteen (14) days of the receipt of the written identification of proposed changes, comments or questions regarding the proposed search terms, the parties will meet and confer in a good faith attempt to reach a list of mutually agreeable search terms applicable to Producing Party.

g. Any remaining disputes shall be presented to the Court within ten (10) business days of the conclusion of the meet and confer process.

h. Upon reasonable request, the Producing Party also agrees to quality check a proposed set of search terms by selecting a statistically random sample (based upon a 95% confidence level with a margin of error of +/-5%) of ESI within the search boundary that did not hit the search terms ("Nulls Set Sample"). If responsive documents are found during the Null Set Sample, the Producing Party agrees to produce the responsive documents separately. If necessary, the parties will then meet and confer to determine if any modification to the proposed set of search terms is needed to ensure substantive, meaningful responsive documents are not missed.

i. Notwithstanding the above, the Parties reserve their right to reproduce prior document productions from other matters, hard copy documents, or other collections of documents that are amenable to a linear review without utilizing any agreed upon search terms. Further, the search terms contemplated by this protocol will govern productions made in connection with the requests for production of documents, unless otherwise agreed by the parties or order by the Court.

j. If a Producing Party determines that a set of agreed search terms or search terms ordered by the Court (collectively "Operative Search Terms") as applied to any particular data set(s) for

culling or identification purposes results in the identification of an unduly overbroad set(s) of ESI (either because of total volume or number of irrelevant documents identified), the Parties shall meet and confer in good faith in an attempt to revise the Operative Search Terms. Should the Parties be unable to reach such an agreement revising Operative Search Terms, the Parties may seek relief from the Court.

k. The Parties reserve all rights to request additional search terms be run on the initial set of all collected ESI, including any custodian data sources, to the extent that discovery demonstrates that the Operative Search Terms resulted in substantive, meaningful responsive documents being omitted from the operative data set for further review.

3. Application of Search Terms

a. To the extent the Producing Party applies the Operative Search Terms for culling and identification purposes to any particular set(s) of ESI that will ultimately be subject to review, the search terms will be run against all ESI (e.g., Word, Excel, PowerPoints, emails) in the set(s) of collected ESI, including emails and their attachments. Any document returned by the Operative Search Terms will be within the scope of the ESI to be analyzed by the Producing Party for responsiveness to the opposing parties' document requests.

b. All Operative Search Terms will be run in a non-case sensitive manner, except as specifically identified otherwise.

c. The actual search syntax utilized by the search tool for the search will be identified to the Receiving Party.

d. The search terms shall be used to identify potentially responsive ESI within a particular set(s) of ESI and will be subject to further review consistent with the Parties' propounded discovery requests, the Parties' objections, and any applicable laws and regulations and court orders.

e. The fact that any ESI is identified by the Operative Search Terms discussed above does not mean that such document necessarily should be produced. For example, ESI may be privileged or not otherwise discoverable (e.g., "Protected Data").

f. To the extent that Producing Parties find a population of unsearchable ESI in any particular set(s) of ESI on which they are using the Operative Search Terms to identify potentially responsive documents and the Producing Party believes there is a reasonable likelihood that this unsearchable population contains potentially relevant information, the Producing Party will notify the Receiving Party and the Parties will meet and confer in good faith to determine a reasonable process to identify potentially responsive documents.

4. Discrete Document Collections

The parties reserve their rights to request that no electronic culling be applied to discrete document collections that are identified, as a whole, to be relevant to the claims and defenses in this litigation.

5. TAR Tool

Any Party using a TAR tool for the purpose of determining relevancy of documents to be produced in this Action shall disclose the specific TAR tool to be used within seven (7) business days of the entry of this TAR Protocol or within seven (7) business days of determining the TAR tool that the Party will be using in this Action.

6. Scope of Relevancy

The Producing and Receiving Party shall meet and confer in an attempt to reach an agreement on the objective of the TAR exercise (i.e., the scope or categories of documents to be identified or excluded by the use of the TAR tool) based upon the Complaint, discovery requests served by the Parties and objections and responses thereto, and any applicable Court guidance. This will lead to a final set of categories of relevant information for which to train TAR.

7. TAR Review Population(s)

a. The Producing Party shall disclose to the Receiving Party the review population on which TAR will be applied (the "TAR Review Population"). This will include the identification of the custodians and non-custodial sources subject to TAR. The Producing Party shall disclose any custodians and non-custodial sources it will not use TAR on.

b. The Parties recognize that certain types or categories of documents may not be appropriate for TAR. The Producing Party shall disclose to the Receiving Party those types or categories of documents that may be excluded from a TAR Review Population and subject to other means of search and review, including, but not limited to, any: (i) documents that lack sufficient text, including certain Excel spreadsheets and other non-text based documents, e.g., photographs or image files, schematics or CAD files, audio or video files, etc.; (ii) documents above an agreed-upon file size; (iii) documents with handwritten annotations; (iv) documents of such poor Optical Character Recognition ("OCR") quality that it would be ineffective to subject them to TAR-based text classification; (v) document sets that the Parties agree will be reviewed by humans in their entirety; and/or (vi) documents already determined to be responsive on the basis of another process, such as inclusion in a discrete document population or through human review.

c. To the extent a Producing Party identifies any types of documents in a TAR Review Population that it has reason to believe will not be or are not being classified effectively by the TAR tool, the Producing Party shall identify (by source/custodian and file type) the excluded documents from the TAR Review Population. The Parties shall meet and confer to discuss any final requirements to search and review that population.

d. The Producing Party shall disclose to the Receiving Party the total number of documents in the TAR Review Population, as well as the types or categories of documents excluded from the TAR Review Population.

e. The Producing Party may remove "junk" emails from the TAR Review Population based upon sender domain name(s) or address(es). If done, the Producing Party will disclose to the Receiving Party the criteria used to identify such "junk" emails and the Parties shall meet and confer to discuss whether any such emails should be included in the TAR Review Population or otherwise reviewed.

f. Any document sets included in the TAR Review Population shall be de-NISTED.

g. TAR makes relevancy predictions based upon a document's text. Within the TAR Review Population, there may be 100% textual duplicates. Only a single copy of a 100% textual duplicate will be reviewed by the TAR tool (the master copy). Any 100% textual duplicate copies will receive the same responsiveness decision as the master copy that was reviewed by TAR.

8. TAR Training Process

a. The Producing Party shall take a random sample generated based upon 95% confidence, +/- 2% margin of error in the TAR Review Population to estimate the richness. This random sample, along with the documents described in Paragraph 9(c) below, will then be used as the "Initial Training Set" for TAR Review. All random samples and exemplars used for training purposes will be tracked so they can be identified at any time.

b. All responsive and non-responsive documents from the random sample, regardless of privilege status, shall be included with the exemplars described below in the Initial Training Set to be used for the purposes of training the TAR tool.

c. At least 200 document exemplars shall be identified by the Producing Party. At least 100 of the document exemplars shall be responsive and shall include at least ten (10) representative exemplars for each of the categories described in Paragraph 6 above. The remaining documents may be either responsive or non-responsive exemplars. These

exemplars will be combined with all the documents from the random sample identified in Paragraph 7.a. above to form the Initial Training Set. The Initial Training Set shall be used to start the training of the TAR tool.

d. Following application of the Initial Training Set, the TAR tool will automatically select for review the documents next most likely to be relevant (i.e., the most-highly ranked, not-yet-reviewed documents) in the TAR Review Population, as well as a selection of documents chosen by the TAR tool to amplify its learning. Every such document shall be reviewed and coded for responsiveness.

e. The first 1,000 documents reviewed after the Initial Training Documents are submitted will be identified and tracked so it can be referenced at any time.

f. The predictive model the TAR tool uses will update itself continuously, using all coded documents, regardless of how those documents are selected for review. Documents shall continue to be reviewed for responsiveness.

9. Supplemental Collections After TAR Has Begun

a. The Producing Party shall disclose if the review will involve supplemental collections and loads to the TAR tool (hereafter called "Supplemental TAR Waves"). The Producing Party shall determine if supplemental collections can be merged into the TAR Review Population, or if a different review will be conducted on the supplemental collection, which may include full human review or a separate instance of TAR. The Producing Party shall disclose to the Receiving Party how it will search and review supplemental collections.

b. For all Supplemental TAR Waves, when that Wave is incorporated into the TAR Review Population, review as provided in Section 6 will pause, and a random sample generated based upon 95% confidence, +/- 2% margin of error will be taken from the Supplemental TAR Wave set.

c. In addition, the Producing Party will determine if any other exemplar documents need to

be identified in the Supplemental TAR Wave to be seeded into TAR at that point in time. The sample documents, plus any exemplars, will be fed into TAR to update the classifier.

d. After that point, review will continue pursuant to Steps 6 below.

10. Review and Review Quality Control

a. Review shall continue using the priority review queue. The predictive model the TAR tool uses will update itself continuously, using all coded documents, regardless of how those documents are selected for review. The human review team shall continue to review the documents the priority review queue presents to the team. This iterative process continues until the Producing Party can reasonably conclude that further review is unlikely to yield further relevant documents with sufficient quantity or materiality to justify continuing per Paragraph 11.

b. During the life of review, the Producing Party shall engage in the following review Quality Control Process on a regular, ongoing basis. This process is used to confirm that the human coding decisions are as accurate and consistent as possible:

i. The Producing Party shall take a 10% random sample of documents coded by humans for responsiveness during the TAR review. A QC reviewer(s) shall re-review the documents for responsiveness to ensure the accuracy of the human review is reasonable. If the responsiveness coding accuracy is maintained at a reasonably high level for a continued period of time for the same set of reviewers (a minimum of three weeks), the Producing Party may at that point lower the random sample sizes to 5%.

ii. The Producing Party shall review all documents that the TAR tool gives a high classification score (i.e., 95 or above), but that the human review team has coded non-relevant to confirm the human coding decisions.

iii. To the extent the TAR tool has a "consistency report" or similar report that shows documents that the TAR tool believes are inconsistently coded for responsiveness, the

Producing Party shall review and confirm the coding of those documents on a regular basis.

iv. The Producing Party shall maintain a decision log for the human review team to follow that provides attorney work-product guidance on relevancy calls for questionably relevant documents and common errors that may become evident through the QC Process.

11. Review Stopping Point

a. TAR will continue until the Producing Party can reasonably conclude that further review is unlikely to yield further relevant documents with sufficient quantity or materiality to justify continuing.

b. Factors to consider when determining the TAR Review Stopping Point is as follows:

i. The human review team has identified a reasonable number of documents (at least 85% recall) as compared to the Richness estimate in Paragraph 7.a. above.

ii. The last 1,000 documents reviewed before stopping do not contain a significant number of responsive documents, *and* none of those relevant documents is novel or more than marginally relevant.

c. After stopping TAR review, the last 1,000 documents reviewed will be identified and tracked so they can be referenced at any time.

d. After stopping TAR review, the Producing Party shall generate a report that details (i) the total number of responsive and non-responsive documents in the random sample in Paragraph 7(a), (ii) the total number of documents that were reviewed before stopping, (iii) the total number of documents coded responsive by the human review team in the last 1,000 documents before stopping (i.e., the last 1,000 documents), (iv) the total number of documents coded non-responsive by the human review team in the last 1,000 documents before stopping, (v) the total number of documents coded "Technical Difficulty" in the last 1,000 documents before stopping, and (vi) identifies by Bates number any responsive

documents produced that were located in the last 1,000 documents before stopping.

e. The Producing Party shall provide a copy of the report as set forth in Paragraph 11(d) to the Receiving Party within fourteen (14) business days of stopping review. The Parties will meet and confer to the extent the Parties disagree regarding the TAR Review Stopping Point.

12. Validation Process

a. After stopping TAR, the Producing Party shall conduct validation according to the sampling protocol described below and in Appendix A to this TAR Protocol.

b. The TAR Review Population includes all documents that were collected to which the TAR process was applied. The TAR Review Population shall be partitioned into two subcollections:

i. Documents reviewed by the human review team ("Subcollection A(1)"); and

ii. Documents deemed non-responsive by the TAR tool and excluded from manual review as the result of the TAR process ("Subcollection A(2)").

c. The Producing Party shall disclose the total number of documents in Subcollection A(1) to the Receiving Party, along with a breakdown of the total number of responsive, non-responsive, and documents coded as "Technical Difficulty" in that set.

d. The Producing Party shall disclose the total number of documents in Subcollection A(2). A sample shall be drawn from this Subcollection consisting of the following: 1,000 documents selected at random (the "Validation Sample").

e. Each document in the Validation Sample shall be reviewed and coded as responsive or non-responsive, and as privileged or non-privileged, by a Producing Party subject matter expert ("SME") who is knowledgeable about the subject matter of the litigation. This shall be an attorney who is familiar with the requests for production, the issues in the case, and the relevance criteria agreed to in the TAR Training Process set forth in Paragraph 6 above.

f. Once the coding in Paragraph 12(e) has been completed, the Producing Party shall identify and produce all responsive, non-privileged Validation Sample documents.

g. Finally, the Producing Party shall promptly provide the statistics and recall estimate detailed in Appendix A to this TAR Protocol based upon the agreed-upon coding determinations. If the measurement shows that the Producing Party has met a recall target at or above 85%, the review process will be deemed reasonable. To the extent the Receiving Party believes the responsive documents are very important to the case, the parties will meet and confer to discuss if any further searches should be taken to find documents like those. However, there will be no further TAR training or review required. If the Receiving Party believes the estimated recall achieved is not reasonable and proportionate to the matter, the parties will meet and confer to discuss further steps, if needed, for review. If the parties are unable to agree on whether the review is reasonable, the matter shall be submitted to the Court for resolution.[1]

h. The Parties reserve all rights to request additional searches and review be conducted on the initial set of all collected ESI, including any custodian data sources, to the extent that discovery demonstrates that the TAR review resulted in substantive, meaningful responsive documents being omitted from the production.

[1] The parties recognize that the inherent nature of the TAR Review means that some amount of relevant documents will be coded by the TAR tool as "irrelevant." The fact that relevant documents are coded as "irrelevant" does not impact the presumption that the TAR Review is reasonable to the extent the validation determines that the TAR tool is operating at our above the agreed 85% recall rate. The parties agree to meet and confer regarding whether and to what extent action other than additional TAR training and review should be undertaken to search for and produce similar responsive documents.

APPENDIX A

Method of Recall Estimation

An estimate of recall shall be computed to inform the decision-making process described in Paragraph 12(g) of the Validation Process. The estimate of recall shall be derived as described below. It should be noted that, when conducted by an SME pursuant to Paragraph 12 of the Validation Process, a recall estimate on the order of 85% or above shall be deemed to be a reasonable review (i.e., high-quality) review. A recall estimate somewhat lower than this does not necessarily indicate that a review is inadequate; the final determination will also depend on the quantity and nature of the documents that were missed by the review process.

Recall Estimation Method for the TAR Review Process:

- The number of responsive documents found = number of responsive documents in Subcollection A(1).
- The estimated number of responsive documents not found = size of Subcollection A(2) × the number of responsive documents in Subsample A(2) ÷ 2,000.
- Estimated recall = the number of responsive documents found ÷ (the number of responsive documents found + the estimated number of responsive documents not found).

AGREED AND STIPULATED TO:

Dated: To be added

OF COUNSEL:

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[Placeholder for Britannia signature block]

[Placeholder for Supernus signature block]

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Counsel for Plaintiffs Sage Chemical, Inc. and TruPharma, LLC.

SO ORDERED this ____ day of _____, 2023.

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE

Exhibit 2

PUBLIC VERSION FILED
NOVEMBER 16, 2023

Buck, Tracy B.

From: Knoepfler, Aliana C. <AKnoepfler@winston.com>
Sent: Friday, August 4, 2023 12:52 PM
To: Shotlander, David S.; Lipkin, Gary W.; Streifthau-Livizos, Michelle C.; Monk, II, Charles O.; Rosenfeld, Jordan D.; Moore, Daniel M.; Danilewitz, Justin C.; Stoviak, John F.; Brockmeyer, Michael; Vakharia, Aakruti G.; Labaton, Ralph E.
Cc: Dobie, W. Gordon; Torpey, Susannah; Duxstad, Lauren; Olsen, Matthew; Rebecca Butcher; cree@lrclaw.com
Subject: Sage Chemical et al. v. Supernus et al. - Search Terms
Attachments: Initial Search Terms Proposed to Supernus August 4, 2023.docx

This Message originated outside your organization.

David,

Attached are proposed search terms for Plaintiffs' Requests for Production to Defendants. We may have some additional small edits from our vendor, but we wanted to get these out as quickly as possible to get search term negotiations started. Please let us know if Defendants will be providing proposed search terms for Defendants' Requests for Production to Plaintiffs.

In addition, could you please provide Supernus's updated position on date ranges by no later than Wednesday of next week? Please also provide Supernus's availability for meet and confers on: (1) Paragraph 6 of the TAR Protocol for the end of next week; (2) Supernus's responses to the attached proposed search terms for the week after next; and (3) Supernus's responses to Plaintiffs' First Set of Interrogatories for the beginning of the week after next.

Thank you,
Aliana

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Search Terms Proposed by Plaintiffs for RFPs to Defendants on August 4, 2023

	Search Terms	Indicative Requests
1.	Apokyn	For TAR
2.	Apokyn AND (agree* OR MOU OR understanding OR contract)	1
3.	"Understanding for the Supply of Pens"	1(a)
4.	"Exclusive Supply of Pens"	1(b)
5.	Apokyn AND Supply AND Pens	1(c)
6.	Commercialization w/3 "Supply Agreement"	1(d)(e)
7.	Sale And Purchase And USWM	1(f)
8.	Apokyn AND (agree* OR MOU OR understanding OR contract) AND (distrib* OR commercial* OR supply OR pharmac*)	1(g)(h)
9.	Apokyn AND ("data room" OR "Project Rye")	2 * ***Defendants should supply any alternative code names***
10.	(Apokyn OR generic OR apomorphine) AND (FDA OR fda.gov OR food w/2 drug OR "Drug Administration")	3
11.	Organization* w/2 Chart	4
12.	Generic	5, 21
13.	(Becton OR BD) AND (pen OR RLP OR RLD OR "restricted transaction" or milestone)	6
14.	Sage	20
15.	Trupharma OR Tru w/2 Pharma	20
16.	Substitut*	22
17.	(board OR director) AND (Apokyn OR generic OR pen* OR RLD OR RLP OR substitut* OR tactics OR lifecycle OR citizen OR Lemonade OR antitrust OR (anti w/2 trust) OR "false advertising" OR liability OR FTC OR "trade commission" or DOJ OR (department w/3 justice) OR complain* or litig* or lawsuit)	23
18.	Sample AND (Apokyn OR inject* OR pen OR RLD OR RLP OR cartridge OR FDA OR "Food & Drug" OR test*)	24
19.	(Apokyn OR generic OR apomorphine OR pen OR cartridge) AND (ANDA OR "Abbreviated New Drug Application" OR "New Drug" OR NDA OR 021264)	25(a)
20.	(FDA OR food w/2 drug) AND approv* AND (Sage OR generic OR cartridge)	25(b)
21.	"citizen petition" OR CP OR "CP initiative"	25(c)(e)(g)(h)
22.	(FDA OR food w/2 drug) AND den* AND petition	25(d)
23.	(Delay OR slow OR block or stop) AND (ANDA OR "Abbreviated New Drug Application" OR 021264 OR approv*)	25(i)

Search Terms Proposed by Plaintiffs for RFPs to Defendants on August 4, 2023

24.	Petition AND (merit OR bas* OR argu* OR succeed OR den* OR fail OR substant* OR support* OR complicat*)	25(j)
25.	Lemonade	26
26.	(agree* OR MOU OR understanding OR contract) AND (apomorphine OR cartridge OR inject* OR pen* OR generic OR exclu* OR distrib* OR "counter detailing" OR deal w/5 competitor* OR substitut* OR sample)	27
27.	(Becton OR BD) AND (restricted OR exclus* OR pay* OR notice OR exten* OR compet* OR analys* OR financ*)	28
28.	(Michael /3 Brown) OR (Kristen /3 Gullo) OR (Breck /3 Jones) OR (Paul /3 Jones) OR (Paul /3 Breckinridge) OR (Stephanie /3 Montgomery) OR (Pamela /3 Sheehan) OR (Henry /3 "van den Berg") OR (Herbert /3 Warren) or (Lee /3 Warren) OR (Mark /3 Christodoulou) OR (Dieter /3 Jebing) OR (Michael /3 McWhan) OR (Robert /3 Wood) OR **[Defendants to provide email extensions]**	29 ***For Supernus searches***
29.	(Kevin /3 Anderson) OR (Jeff /3 Bozick) OR (Arianne /3 Breiteneicher) OR (Doug /3 Conner) OR (Timothy /3 Dec) OR (Gary /3 Ellexson) OR (Cindy /3 Happel) OR (Todd /3 Horich) OR (James /3 "Patrick Kelly") OR (Jack /3 Khattar) OR (Brandon /3 King) OR (Tami /3 Martin) OR (Ted /3 Nix) OR (Gregory /3 Patrick) OR (Taylor /3 Raiford) OR (Bryan /3 Roecklein) OR (Bill /3 Soucie) OR (Mark /3 Christodoulou) OR (Dieter /3 Jebing) OR (Michael /3 McWhan) OR (Robert /3 Wood) OR **[Defendants to provide email extensions]**	29 ***For USWM searches***
30.	(Kevin /3 Anderson) OR (Jeff /3 Bozick) OR (Arianne /3 Breiteneicher) OR (Doug /3 Conner) OR (Timothy /3 Dec) OR (Gary /3 Ellexson) OR (Cindy /3 Happel) OR (Todd /3 Horich) OR (James /3 "Patrick Kelly") OR (Jack /3 Khattar) OR (Brandon /3 King) OR (Tami /3 Martin) OR (Ted /3 Nix) OR (Gregory /3 Patrick) OR (Taylor /3 Raiford) OR (Bryan /3 Roecklein) OR (Bill /3 Soucie) OR (Michael /3 Brown) OR (Kristen /3 Gullo) OR (Breck /3 Jones) OR (Paul /3 Jones) OR (Paul /3 Breckinridge) OR (Stephanie /3 Montgomery) OR (Pamela /3 Sheehan) OR (Henry /3 "van den Berg") OR (Herbert /3 Warren) or (Lee	29 ***For Britannia searches***

Search Terms Proposed by Plaintiffs for RFPs to Defendants on August 4, 2023

	/3 Warren) OR **[Defendants to provide email extensions]**	
31.	(restr* OR limit* OR third part*) AND (dispens* OR distrib* OR substitut* OR replac* or supply* OR sell* OR transfer*) AND (Apokyn OR apomorphine OR cartridge* OR inject* OR pen* OR generic OR "USWM Product")	30
32.	(patient OR user OR individual OR access) AND (Pen* OR Inject* OR Apokyn) AND (apomorphine OR cartridge* OR generic OR Sage)	31(a)(b) ***Defendants should supply any additional ways they refer to patients**
33.	(patient OR user OR individual OR access) AND (Pen* OR Inject* OR Apokyn) AND (prescript* OR prescribe* OR dispens* or pharmacy)	31(c) ***Defendants should supply any additional ways they refer to patients**
34.	(difficult* OR problem OR hard OR ability) AND (patient OR user OR individual) AND (access* OR prescri* OR purchas* OR receiv* OR dispens*) AND (Apokyn OR apomorphine OR cartridge* OR inject* OR replace* OR pen* OR generic)	31(d) ***Defendants should supply any additional ways they refer to patients**
35.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen* OR generic) AND (medinfo.uswm@apcerls.com OR complain* OR harm* OR access* OR advers* OR ability OR inability OR able OR unable OR restrict* OR limit*)	31(e)
36.	(request OR obtain* OR find* OR found OR buy* OR bought OR get) AND (Apokyn OR apomorphine OR cartridge* OR inject* OR pen* OR generic)	31(f)
37.	(order OR get OR prescri* OR obtain OR request) and (pen or replace*)	31(g)
38.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen*) AND (forecast* OR project* OR analys* OR pric* OR cost* OR revenue* OR discount* OR profit* OR margin* OR sale* OR financ* OR account*) OR (raise OR increase OR maintain w/3 pric*)	32, 34
39.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen* OR generic) AND (invest* OR stock* OR shareholder* OR shares OR equity OR asset* OR "financial results" OR earning*)	33
40.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen*) AND (payment* OR royalt* OR milestone* OR revenue* OR profit* OR sale*)	35

Search Terms Proposed by Plaintiffs for RFPs to Defendants on August 4, 2023

	AND (Britannia OR BPL OR USWM OR WorldMeds OR Gullo OR Berg OR Jones OR Breckinridge OR Warren OR member)	
41.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen*) AND (cost* OR unit* OR sale* OR profit* OR pric* OR revenue*) AND ("United States" OR FSS OR federal OR govern* OR insura* OR provid* OR benefici* OR patient*)	36
42.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen* OR generic OR Parkinson*) AND (competit* OR market* OR substitut* OR interchang* OR elasti* OR entry OR enter* OR share* OR account* OR customer* OR distribut* OR input* OR access* OR volume* OR sale* OR demand)	37, 38
43.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen* OR Parkinson* OR generic*) AND (compet* OR market* OR deter* OR mitigat* OR entry OR enter* OR protect* OR share* OR barrier* OR block* OR prevent* OR prohibit*)	39
44.	(quality* OR characteristic OR specification) AND (pen* OR RLP OR RLD OR inject*)	40
45.	(Pen* OR RLP OR RLD OR inject*) AND (test OR consider OR use OR apomorphine or Apokyn)	41
46.	(Becton OR BD) AND (exclusiv* OR "Restricted Transaction" OR milestone*)	42
47.	(Becton OR BD) AND (Sage OR generic* OR ANDA OR Beloteca OR Ingenus)	43
48.	(Sage OR TruPharma OR generic* OR apomorphine OR ANDA OR Apokyn OR cartridge* OR inject* OR pen*) AND (pharmac* OR contract* OR agree* OR negotiat* OR Accredo OR Econdisc OR "Express Scripts" OR "Express-Scripts" OR CVS OR Caremark OR "Red Oak" OR McKesson OR Cardinal OR Optum*)	44, 47
49.	Generic AND (cancel OR order OR block OR stop OR drop OR end OR prevent OR dispens*)	45
50.	(Sage OR TruPharma OR generic* OR apomorphine OR ANDA OR Apokyn OR cartridge* OR inject* OR pen*) AND (contract* OR agree* OR terminat* OR end* OR modif* OR chang* OR amend* OR term* OR condition* OR provision* OR section* OR clause* OR violat*	46, 63

Search Terms Proposed by Plaintiffs for RFPs to Defendants on August 4, 2023

	OR prohibit* OR prevent* OR forbid* OR infring* OR illegal OR legal* OR decreas*)	
51.	(Pen* OR inject* OR Apokyn OR apomorphine) AND (replac* OR separate* OR apart OR demand* OR request* OR package* OR provid* OR dispens* OR suppl* OR combin*)	48
52.	(Pen* OR inject* OR replacement) AND (fee* OR pric* OR pay* OR cost* OR charge* OR free)	49
53.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen* OR generic) AND (distrib* OR access* OR foreclos* OR channel* OR network OR pharmac* OR substitut* OR replac* OR block)	50
54.	(generic OR apomorphine OR cartridge*) AND (refill* OR replac* OR pen* OR prescri* OR earn* OR invest*)	51
55.	(antitrust OR anti w/2 trust OR unfair OR compet* OR unlaw* OR false* OR illegal OR legal* OR investigat* OR litigat* OR monopol* OR conspir* OR collud* OR collus* OR cartel* OR settle* OR concern* OR violat* OR complain* OR arbitrat* OR hotline* OR anti w/2 competitive OR liab* OR claim* OR lawsuit* OR FTC OR "Federal Trade Commission" OR DOJ OR Department w/3 Justice)	52[1]
56.	(Apokyn OR 021264 OR 21264) AND (NDA OR "New Drug Application")	54
57.	("Joint Development Committee" OR "JDC" OR "Peripheral")	55
58.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen*) AND (lifecycle* OR protect* OR keep OR maintain OR sale* OR profit* OR margin* OR revenue* OR strateg* OR tactics OR contract OR negot*)	56
59.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen*) AND (marketing /3 plan* OR brand /3 plan*)	57
60.	Apokyn AND ("Dossier" OR "Durable Pen Product")	58
61.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen* OR generic OR Sage OR TruPharma OR "CP" OR "citizen petition" OR	59

[1] Please note we have not included search terms for certain requests that will likely be satisfied through other means (e.g., 53 (documents referenced in initial disclosures), 62 (views of the Apokyn website)) or for which we understand Defendants to currently be standing on their objections (e.g., 68 (document retention policies).

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	exclu*) AND (litigat* OR arbitrat* OR disput* OR legal* OR illegal OR concern* OR complain* OR settle* OR violat* OR liab* OR claim* OR anticompetitive OR anti w/2 competitive OR indemnif* OR contribut* OR lawsuit* OR expos*)	
62.	Apokyn AND only AND (FDA OR (food w/2 drug) OR approv* OR availab*)	60
63.	Generic AND (FDA OR (food w/2 drug) OR approv* OR availab*)	61
64.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen*) AND (investing* OR DOJ OR "Department of Justice" OR HHS OR "Heath and Human Services" OR DHA OR "Defense Health Agency" OR antitrust OR unfair OR fals* OR advertis* OR kickback* OR Medicare OR Bennett OR Chinnapongse)	64
65.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen* OR sample* OR RLD OR generic) AND (restrict* OR limit* OR "third parties" OR specialty OR pharmac*) AND alternat* OR benefit* OR justif* OR reason* OR basis)	65
66.	Apokyn AND (restrict* OR limit* OR "third parties" OR specialty OR pharmac*) AND (necessary OR need* OR alternat*)	66
67.	(apomorphine OR cartridge* OR generic) AND (test* OR inspect* OR evaluat* OR examin* OR assess* OR analy*)	67
68.	Generic AND (Apokyn OR apomorphine OR cartridge OR inject* OR pen) AND (FDA OR (food w/2 drug) OR develop* OR approv* OR market* OR design* OR manufactur* OR apply OR application*)	69
69.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen*) AND (distrib* OR market*)	70
70.	Generic AND (FDA OR (food w/2 drug) OR approv* OR react* OR respon* OR plan OR tactic*)	71
71.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen* OR generic OR sample* OR RLD OR RLP) AND **[Defendants to provide a list of all relevant agents, distributors, pharmacies, and PBMs]**	72
72.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen* OR generic OR Sage OR TruPharma) AND (forecast* OR project* OR	73

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	analys* OR pric* OR cost* OR revenue* OR discount* OR profit* OR margin* OR sale* OR financ* OR account* OR volume* OR penetrat* OR approv* OR launch* OR FDA OR (food w/2 drug))	
73.	Apomorphine OR Parkinson* OR (off w/3 episode*) AND pric*	74
74.	(Apokyn OR apomorphine OR cartridge* OR inject* OR pen* OR sample* OR RLD OR RLP OR generic) AND (restr* OR limit* OR third part* OR dispens* OR distrib* OR substitut* OR replac*) AND (purpose* OR reason OR effect* OR affect*)	75